REMARKS

Applicants have received and carefully reviewed the Office Action mailed November 9, 2009. Currently, claims 1-40 remain pending of which claims 11-16, 19, 21-24, and 34-40 were previously withdrawn from consideration. Claims 1-10, 17-18, 20, and 25-33 have been rejected. With this Amendment, claims 1, 34, and 36 have been amended. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 U.S.C. § 102

On page 2 of the Office Action, claims 1-8, 17-18, and 29-30 were rejected under 35 U.S.C. §102(b) as being anticipated by Bleam et al. (U.S. Patent No. 6,143,016). After careful review, Applicants respectfully disagree.

Turning to claim 1, which recites:

> 1. A catheter assembly comprising:
> a catheter, the catheter comprising a catheter shaft;
> a first rotatable sheath, the first rotatable sheath being disposed about a portion of the catheter shaft, the first rotatable sheath having a length substantially less than that of the catheter shaft, the first rotatable sheath being expandable from a reduced sheath state to an expanded sheath state, in the reduced sheath state the first sheath being rotatable about the portion of the catheter shaft;
> a first guidewire housing, the first guidewire housing defining a first guidewire lumen for passage of a first guidewire therethrough, at least a portion of the first guidewire housing being engaged to an outer surface of the first rotatable sheath;
> a first stent, the first stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the stent being disposed about at least a portion of the first rotatable sheath and at least a portion of the first guidewire housing; and
> a second stent, the second stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the second stent being adjacent to the first stent.

Nothing in Bleam et al. appear to disclose many elements of claim 1, including for example, "a first rotatable sheath, the first rotatable sheath being disposed about a portion of the catheter shaft, the first rotatable sheath having a length substantially less than that of the catheter shaft, the first rotatable sheath being expandable from a reduced sheath state to an expanded sheath state, in the reduced sheath state the first sheath being rotatable about the portion of the catheter shaft", "a first guidewire housing, the first guidewire housing defining a first guidewire lumen

for passage of a first guidewire therethrough, at least a portion of the first guidewire housing being engaged to an outer surface of the first rotatable sheath", or "a first stent, the first stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the stent being disposed about at least a portion of the first rotatable sheath and at least a portion of the first guidewire housing".

Instead, Bleam et al. appear to disclose an assembly 10 for deploying stent 12 including a balloon catheter 14 having a catheter shaft 15. The assembly 10 appears to also include a sheath 28 having a distal portion 34 and a proximal portion 36. The distal portion 34 of the sheath 28 appears to include an elastic, expandable material that can be expanded by outward pressure from within sheath 28. The proximal portion 36 appears to be formed of a material to enhance the pushability of the sheath 28. A stent 12 appears to be positioned on the distal portion 34 of the sheath for delivery into the vessel. The sheath 28 appears to have a proximal portion length 40 that is several times the distal portion length 42. Notably, for example, column 3, lines 39-46 of Bleam et al. states:

> The tubular sheath proximal portion preferably has a length of at least 50 cm, depending on the particular application and body lumen to be treated. The length of the proximal portion should be sufficient to allow the proximal end of the sheath to be outside of the patient while the distal portion that bears the stent is at the desired deployment site inside the body lumen.

In addition, column 6, line 59 through column 6, line 11 states:

> The sheath 28 of FIG. 2 has an outer diameter 50 sized to pass within a body lumen. The sheath 28 preferably has a length 52 that allows the sheath distal end 30 to be positioned at a desired treatment site in a body lumen while the sheath proximal end 32 is positioned outside of the body lumen and patient, so that a user can manipulate the sheath 28 by grasping and maneuvering the sheath proximal end 32. Maneuvering the proximal end 32 of sheath 28 provides relative axial movement between the sheath distal end 30 and the dilatation balloon 22 so that the stent 12 is thereby positioned at the desired treatment site. The proximal portion 36 may include a handle 53 or similar manipulation device by which a user can grasp and move the sheath 28 axially over catheter shaft 15.
>
> Different sheaths can have various lengths, depending on the particular application. For example, in a balloon angioplasty procedure where a sheath is used to deploy a stent in a coronary artery (as shown in FIG. 5), the sheath length 52 is generally at least 50 cm in length, and will preferably be on the order of 100 cm to 140 cm in length. The precise length will be determined by the application.

As can be seen from these passages, the sheath 28 appears to extend from a distal region of the catheter shaft that includes a balloon to a position outside of the body lumen and patient. As such, the sheath 28 of Bleam et al. does not appear to have a length substantially less than that of the catheter shaft 15. Thus, nothing in Bleam et al. appear to disclose "the first rotatable sheath having a length substantially less than that of the catheter shaft", as recited in claim 1.

While Applicants respectfully assert that original claim 1 is patentable over Bleam et al., in the spirit of cooperation, Applicants have amended claim 1 to further distinguish the catheter assembly of claim 1 from Bleam et al. Specifically, claim 1 has been amended to recite "at least a portion of the first guidewire housing being engaged to an outer surface of the first rotatable sheath" and "in the reduced stent state the stent being disposed about at least a portion of the first rotatable sheath and at least a portion of the first guidewire housing". Nothing in Bleam et al. appear to disclose such features.

As noted in MPEP § 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In view of the foregoing, Bleam et al. cannot be seen as teaching each and every element of claim 1, and also cannot be seen to disclose all of the elements of claim 1 arranged or combined in the same way as recited in claim 1. Further, there appears to be no reason to modify the teachings of Bleam et al. to arrive at the claimed catheter assembly. For at least these reasons, claim 1 is believed to be patentable over Bleam et al. For similar reasons and others, claims 2-8, 17-18, and 29-30, which depend from claim 1 and include additional distinguishing features, are believed to be patentable over Bleam et al.

Claim Rejections – 35 U.S.C. § 103

On page 3 of the Office Action, claims 9-10, 20, 25-28, and 31-33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bleam et al. (U.S. Patent No. 6,143,016). After careful review, Applicants respectfully disagree. As discussed previously, claim 1 is believed to be patentable over Bleam et al. For similar reasons and others, claims 9-10, 20, 25-28, and 31-33, which depend from claim 1 and include additional distinguishing features, are also believed

to be patentable over Bleam et al.

Further, Applicants respectfully traverse and do not concede any assertions made in the Office Action, specifically the assertions on page 3 of the Office Action. Specifically, the Office Action states "[i]t would have been obvious to one of ordinary skill in the art to provide the stent with either reduced diameter or tapered diameter at the proximal end of the stent in the collapsed state as recited in the claims as this configuration would prevent the proximal end of the stent to injure a blood vessel wall during deployment of the stent", yet the Office Action has failed to provide any evidence for this conclusory statement. The Office Action also makes the following assertions: "the therapeutic materials are well known for treatment a blood vessel"; "these coatings are well known to use for a catheter device to facilitate the deployment of a catheter in a blood vessel"; and "these materials are well known to use for making a catheter device to facilitate the deployment of a catheter in a blood vessel". Applicants respectfully submit that these assertions are merely conclusory in nature and the Office Action has failed to provide any documentary evidence to support these assertions. Applicants note MPEP § 2144.03 state "[i]t is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697". As such, Applicants respectfully request documentary evidence to support these assertions if the rejection is to be maintained.

Further, if the Office Action is attempting to take Official Notice, Applicants respectfully traverse the taking of Official Notice. Applicants note that MPEP § 2144.03 part "A" states:

> Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)).
>
> It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 (emphasis added).

MPEP § 2144.03 part "B" states:

> If such notice is taken, the basis for such reasoning must be set forth explicitly. The examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. See *Soli*, 317 F.2d at 946, 37 USPQ at 801; *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. The applicant should be presented with the explicit basis on which the examiner regards the matter as subject to official notice **>so as to adequately traverse the rejection< in the next reply after the Office action in which the common knowledge statement was made (emphasis added).

MPEP § 2144.03 part "C" states:

> If applicant adequately traverses the examiner's assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained. See 37 CFR 1.104(c)(2). See also *Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697 (emphasis added).

Applicants submit that the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known, particular in combination with the other elements of the claim. Per MPEP 2144.03(C), Applicants respectfully traverse the taking of Official Notice and request documentary evidence be provided supporting the rejection and clarification in the next office action if the rejection is maintained.

Conclusion

Reconsideration and further examination of the rejections are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Tracee Eidenschink et al.

By their Attorney,

Date: 2-2-2010

J. Scot Wickhem, Reg. No. 41,376
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, MN 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349